

REMARKS

The last response filed by Applicant on September 1, 2006 included amendments to the specification in response to objections raised by the Office in the Office Action mailed March 3, 2006. Applicants represented that the amendments were sufficient to overcome the objections identified by the Office. The Office Action (Final Rejection) mailed November 17, 2006 did not refer to these amendments and did not reiterate the objections. Applicant would appreciate confirmation from the Office that the amendments have been entered and the objections overcome.

Applicants last response also included amendments to claim 1 that the Office asserts in the Final Rejection results in the amended claim being "similar" to withdrawn Claims 13-21 and therefore the Office has treated amended claim 1 and those claims dependent thereon (claims 2-5 and new claims 37-40) as "constructively" "directed to a non-elected invention," citing 37 CFR 1.142(b) and MPEP § 821.03. This interpretation is traversed.

The claims of the subject application were originally subject to a restriction requirement pursuant to an Office Action mailed Jan. 13, 2006. That action identified two groups of claims subject to restriction as follows:

- "I. Claims 1-12, drawn to apparatus for determining the condition of a region of tissue comprising a cup or housing having first and second openings, an electrode and a source of suction, classified in class 600, subclass 372.
- II. Claims 13-36, drawn to methods and apparatus for determining a condition of breast tissue or the location of a tumor using a pair of electrodes, classified in class 600, subclass 547."

In a response mailed Feb. 10, 2006, Applicant elected the invention of Group I, corresponding to claims 1-12, for prosecution in the present application. As can be seen from the above quoted language, the restriction requirement was directed to a distinction between apparatus and method claims. The restriction was not based on a limitation to "epithelial" tissue and therefore it is inappropriate to introduce a new condition or feature into the original restriction in response to Applicant's last amendment. Neither the Rules nor the MPEP section cited by the Office justify withdrawal from consideration of the amended claims in view of the nature of the amendment introduced by Applicant. Although the present communication removes the reference to "epithelial" in claim 1, new claims 41-43 include such a limitation so that this issue is still relevant in view of the instant amendments. The instant claim amendments are shown relative to the previously submitted amendment which presumably was entered as of right. Entry, consideration and examination of the instantly amended claims are requested.

The Office Action mailed March 3, 2006 has been carefully reviewed, and the instant amendments and remarks are provided in response thereto.

Claims 6-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Hirsch et al.* ('935). *Hirsch* is said to teach an apparatus comprising the elements identified in original claim 1, including an apparatus that has a cup having an interior and first and second openings as well as an electrode disposed within the interior. *Hirsch* is said also to teach a source of suction that is connected to one of the openings so that when the first opening is placed over a region of tissue and suction is applied to the second opening, an electrical connection is made between the region of tissue to be examined and the electrode. Furthermore, it is said that a

flange surrounds the first opening and that the source of suction can be a syringe or an aspirator. Furthermore, the Office states that *Hirsch* also discloses a measuring device in communication with the electrode to determine an electrical signal from the electrode and that a display device may display the electrical signal from the electrode. This rejection is traversed.

While the Office has described various salient features of *Hirsch* that are generally relevant to the instant invention, there are specific features of *Hirsch* that differ from the present invention in view of the claims as instantly amended. In particular, *Hirsch* describes an apparatus that is specifically designed to allow the internal electrode to make contact with the patient's skin surface when the apparatus is placed at the skin surface. (col. 2, lns. 48-51) To accomplish this, *Hirsch* describes a device wherein the cup housing is made of a resilient, deformable material so that when suction is applied, the wall of the cup deforms, allowing the internal electrode to be drawn down onto the patient's skin to make the required contact. (col. 2, lns. 29-59 and claim 1) In contrast, the apparatus and methods of the instant invention are not directed to making contact with the skin surface directly through an electrical contact that is drawn down to the skin, but rather through "an electroconductive medium" which is a required element of the claims. This feature is completely absent from *Hirsch*. Thus, the amended claims cannot be anticipated under 35 U.S.C. § 102(b).

Furthermore, as discussed in the previous response, the instant apparatus is also designed to allow for the introduction of pharmacological agents in order to challenge transepithelial tissue and thereby further characterize its condition. Instantly amended claims 37 and 40 and new claims 41, 42 and 43 specifically recite that the features of

the apparatus are consistent with determining the condition of an epithelial region of tissue, thereby further distinguishing the present invention from *Hirsch*. Furthermore, the *Hirsch* apparatus, wherein an electrode merely makes contact with the surface of the skin, cannot be used for determining the transepithelial condition of tissue. Withdrawal of this aspect of the rejection is respectfully requested.

In the prior Office Action, claims 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hirsch* in view of *Lundbäck* ('404). The Office explained that *Hirsch*, as described in the previous paragraph, teaches all of the limitations of the claims except that an electroconductive medium is provided to facilitate an electrical connection between the region of tissue to be examined and the electrode. The Office argued that *Lundbäck* teaches that it is known to apply electroconductive agents, such as conductive gel or physiological saline, to tissue in order to improve electrical contact between the skin and a biomedical electrode element. (col. 1, lns. 29-35) It is concluded that it would have been obvious to one having ordinary skill in the art to utilize an electroconductive medium such as a saline solution with an electrode apparatus similar to that of *Hirsch* in order to improve electrical contact between the skin and the electrical element. This rejection is traversed.

To begin with it is important to consider the complete teaching of *Lundbäck* rather than the passing reference cited by the Office. On its way to describing the advance claimed in its patent, in the lines following those cited by the Office *Lundbäck* states that materials such as conductive gel and saline are among contaminants to be avoided:

"It has been found that the contaminants--unless otherwise specified, the term "contaminants" as used hereinafter includes perspiration conductive gel, saline

and the like--often have an unfavourable and unpredictable influence on the signals picked up from the patient through the electrode element, for example in ECG measurements."

(col. 1, lines 35-40)

Therefore, rather than serving as a teaching to improve the electrical skin contact taught by *Hirsch*, *Lundbäck* would be understood to teach that saline and conductive gel are to be avoided.

Furthermore, the use of such materials is particularly inconsistent with *Hirsch*, which is specifically directed to monitoring electrical "characteristics of a patient such as a fetus or a neonate," particularly while still in the womb. (col. 6, lines 40-62) Clearly, *Lundbäck's* use of a material such as saline is irrelevant to use of the *Hirsch* apparatus under such conditions. Additionally, it is an underlying requirement of *Hirsch* that an electrical connection be made by physical contact between the skin and the electrode. The presence of saline or gel between the electrode and the skin surface would be understood to interfere with such direct contact. Additionally, neither *Hirsch* nor *Lundbäck* suggests how such materials could be used in combination with the *Hirsch* apparatus and their arbitrary use would not correspond to the use of an electroconductive medium as set forth in the amended claims and as described in the present application.

Finally it is observed that agents such as an electroconductive medium (ECM) and secondary agents in combination with an ECM are introduced so as to infuse or diffuse into a duct and thereby either improve the electrical measurement of a subsurface epithelial feature or modify the response of such tissues to the agent used. This aspect of the invention is significantly different from both *Hirsch* and

*Lundbäck*, which are both merely directed to electrical measurement of the skin surface.

In summary, *Lundbäck* cannot cure the basic deficiencies in *Hirsch*, particularly since it refers to the use of saline and gel as interfering with electrical contact with the skin surface. The references, either alone or in combination fail to suggest any possibility of affording an improvement to the passage of an electrical current into a duct or beneath the surface of the skin or measuring an electrical property of a tissue region beneath the surface of the skin, such as an epithelial region. Withdrawal of this rejection is respectfully requested.

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hirsch* in view of *Dempsey et al.* ('222). The Office states that *Hirsch* teaches all of the limitations of the claims except for the use of wireless connections between the measuring unit and the electrode and between the measuring device and the display device. *Dempsey* is said to cure those deficiencies, thereby rendering claims 11 and 12 obvious. It is respectfully noted that in view of the underlying deficiencies of *Hirsch* with regard to the present claims, which *Dempsey* does not cure, claims 11 and 12 are similarly allowable in view of the underlying patentability of claim 1. Withdrawal of this aspect of the rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/717,074

Docket No.: DAVIES 3.0-001 CIP I

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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